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REMARKS

At the time of the present Office Action, the present application had Claims 48, 50 and 53-55 under consideration. Claims 1-40 were previously cancelled. Indeed, the above-identified application has had a long history of prosecution and claim amendments. The presently rejected Claims were principally introduced into prosecution upon the filing of a second submission under 37 C.F.R. §1.129(a) dated December 23, 1998. Applicants have outlined the history of the claim amendments below.

The application was filed on August 10, 1990, with 21 original Claims. A preliminary amendment dated September 23, 1991, cancelled Claim 1 and added new Claim 22. Amendments were made to Claims 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11.

In the response submitted April 24, 1992, Claims 2, 3 and 18 were cancelled and Claims 4, 5, 6, 7, 9, 10, 12, 14, 15, 17 and 19 were amended. Further, Claims 20 - 22 were cancelled and essentially rewritten as new Claims 23 - 26.

A further amendment was submitted December 15, 1992, wherein Claims 6, 7, 10, 11, 12, 14, 17, 23 and 26 were amended. In response to a Final Office Action dated March 2, 1993, Claims 9, 14, 17, 19, 23, 24, 25, and 26 were amended and concurrently a Notice of Appeal was filed. An advisory action dated September 27, 1993 indicated the amendment filed in response to the final rejection would not be entered and the Claims remained rejected. An appeal brief was filed March 2, 1994. In response to the Appeal, Appellants received a further non-final Office Action. In reply, Claim 17 was cancelled; Claims 12, 14, 15, 19, 23, 24, 25 and 26 were amended; and Claims 27 - 29 were added.

On July 7, 1995, in response to a Final Office Action dated Feb 14, 1995, Appellants cancelled Claim 16 and amended Claims 9, 12, 19, 23, 24, 25, 26 and 27. The amendment was entered, but the claims remained rejected. A Notice of Appeal was filed. Subsequently, on October 16, 1995, a response was filed under 37 C.F.R. §1.129(a). A Preliminary Amendment filed November 28, 1995 added new Claims 30 - 33. A further amendment dated April 17, 1996 was filed, wherein Claims 4, 13, 14, 19, 23, 24, 25, 26, 28, 29, 30 and 33 were amended and Claims 34 - 37 were added. A non-final Office Action dated September 4, 1996 again rejected

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pending Claims 4 - 7, 9 - 15, 19, and 23 - 37. In response, Claims 11, 15, 26 - 28 and 36 - 37 were cancelled; claims 4, 5, 6, 7, 9, 10, 12, 13, 14, 23, 29, 30, 34 and 35 were amended and Claims 38 - 40 were added. A Final Office Action dated April 1, 1997 was received, and Appellants filed a Notice of Appeal on Oct. 1, 1997, indicating that the rejections of Claims 7, 9 - 10, 12 - 14, 19, 23 - 25, 29 - 35 and 38 - 40 were to be appealed. However, Appellants did not file an Appeal Brief. When a new representative for Appellants reviewed the file, it was discovered that the application was actually abandoned due to filing the October 16, 1995, 37 C.F.R. §1.129(a) submission subsequent to filing the March 1994 Appeal Brief. On December 23, 1998, Appellants filed a timely petition to revive the unintentionally abandoned application and to accept the first submission made under 37 C.F.R. §1.129(a). Additionally, Appellants filed a second submission under 37 C.F.R. §1.129(a) which included an amendment canceling the pending Claims, 4 - 7, 9 - 10, 12 - 14, 19, 23 - 25, 29 - 35 and 38 - 40 and submitting new Claims 41 - 53. Appellants were notified in a communication from the Petitioner's Office dated August 9, 1999 that (i) the petition to revive the abandoned application was granted; (ii) the rules were waived with respect to the first submission under 37 C.F.R. §1.129(a) and said submission was accepted; and (iii) the second submission under 37 C.F.R. §1.129(a) was accepted.

In response to an Office Action dated June 27, 2000, Claims 44, 49 and 51 were amended. A further amendment was filed July 24, 2001, wherein Claims 41, 45, 47, 48 and 50 were amended and Claims 54 and 55 were added. In Response to a Final Office Action dated October 23, 2001, Applicants filed a Notice of Appeal and subsequent Appeal Brief regarding the rejection of Claims 41 - 55. Pursuant to a decision by the Board of Patent Appeals and Interferences mailed December 24, 2003, prosecution of the present case was reopened, due to the vacating of the Examiner's rejections and remand to the Examiner by the Board. In a Response faxed on August 19, 2004, Applicants cancelled Claims 41-47, 49, 51, and 52, and amended Claims 48, 50, and 54, without prejudice.

Applicants again appreciatively note that in a Final Office Action mailed December 1, 2004, the Examiner withdrew a majority of the rejections previously made

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against the Claims. Applicants filed a Response on February 1, 2005, in which Claims 48, 50, 53 and 54 were pending. These are the Claims that are currently pending, as well.

Applicants appreciatively note that the finality of the previous Office Action has been removed. The current rejections are addressed below in the following order:

- 1) Claims 48, 50, 53, and 54 stand rejected under 35 USC §112, second paragraph as allegedly being indefinite;
- 2) Claims 48, 50, 32, and 54 stand rejected under 35 USC §112, first paragraph as allegedly not meeting the written description requirement.

1) The Claims are Definite

The Examiner has rejected Claims 48, 50, 53, and 54, under 35 USC §112, second paragraph, as allegedly being indefinite. While Applicants must respectfully disagree, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, Applicants have amended the Claims to more clearly recite that the indigenous wild-type alkaline serine protease is inactivated. Thus, in regard to Claim 48, Applicants respectfully submit that it is clear that it is the indigenous wild-type extracellular serine protease that is inactivated, as the homologous recombination is performed by transforming with the non-coding regions of the protease. Thus, it is clear that the indigenous wild-type extracellular serine protease is inactivated.

In regard to Claims 50 and 54, Applicants have amended the Claims to recite that the substitutions at positions 160, 212, and 216 are made in the nucleotide sequence encoding the wild-type high alkaline serine protease of *Bacillus novo* species PB 92. The Claims also encompass the derivative PBT 110. The fact that there is no specific SEQ ID NO: is not relevant, as the *Bacillus novo* species PB 92 wild-type high alkaline serine protease is well-described in the application as filed. The identification of amino acid numbers 160, 212 and 216 is simply a matter of sequencing the protease. Indeed, the present Specification provides additional teaching in the substitutions M216Q, S160D, and N212D. Thus, it is clear that Applicants' Claims are definite. No new matter is added in these amendments.

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Applicants respectfully submit that the Claims are definite and request that this rejection be withdrawn.

2) The Written Description Requirement is Met

The Examiner has rejected Claims 48, 50, 53, and 54 under 35 USC §112, first paragraph, as allegedly not meeting the written description requirement. Applicants must respectfully disagree.

The Examiner argues that the Claims are genus Claims that "directed toward several genera: a genus of genes of any nucleotide sequence and structure encoding any wild-type alkaline serine protease of any amino acid sequence and structure . . ." (Office Action, page 3). Applicants must respectfully disagree, as the Claims are limited to the wild-type alkaline serine protease of PB92 or its derivative PBT110, both of which are well-described in the present Specification. As Applicants were working with these strains, it is clear that they had possession of the claimed invention prior to the filing date of the present application. Indeed, a program of producing mutant proteases based on the PB92 wild-type alkaline serine protease was well underway at the time of filing. However, Applicants expressly reserve the right to pursue these and/or broader and/or narrower Claims in subsequently filed applications.

In regards to the regulatory elements, promoter, and 5' and 3' non-coding flanking regions, Applicants must respectfully submit that these are described and exemplified in the various Examples and Figures of the present application. Thus, there is more than sufficient support for the present Claims. Applicants respectfully request that this rejection be withdrawn.

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CONCLUSION

All grounds of rejection and objection of the Office Action of August 12, 2005, having been addressed, reconsideration of the application is respectfully requested. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned at (650) 846-5838.

Respectfully submitted,

Dated: February 6, 2006


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